# Cost-Effectiveness of a Diabetes Self-Management Education and Support Intervention Led by Community Health Workers and Peer Leaders: Projections From the Racial and Ethnic Approaches to Community Health Detroit Trial

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## OBJECTIVE

**To simulate the long-term cost-effectiveness of a peer leader (PL)–led diabetes self-management support (DSMS) program following a structured community health worker (CHW)–led diabetes self-management education (DSME) program in reducing risks of complications in people with type 2 diabetes (T2D).**

## RESEARCH DESIGN AND METHODS

**The trial randomized 222 Latino adults with T2D to *1*) enhanced usual care (EUC); *2*) a CHW-led, 6-month DSME program and 6 months of CHW-delivered monthly telephone outreach (CHW-only); or *3*) a CHW-led, 6-month DSME program and 12 months of PL-delivered weekly group sessions with telephone outreach to those unable to attend (CHW + PL). Empirical data from the trial and the validated Michigan Model for Diabetes were used to estimate cost and health outcomes over a 20-year time horizon from a health care sector perspective, discounting both costs and benefits at 3% annually. The primary outcome measure was the incremental cost-effectiveness ratio (ICER).**

## RESULTS

**Over 20 years, the CHW + PL intervention had an ICER of $28,800 and $5,900 per quality-adjusted life-year (QALY) gained compared with the EUC and CHW-only interventions, respectively. The CHW-only intervention had an ICER of $430,600 per QALY gained compared with the EUC intervention. In sensitivity analyses, the results comparing the CHW + PL with EUC and CHW-only interventions were robust to changes in intervention effects and costs.**

## CONCLUSIONS

**The CHW + PL–led DSME/DSMS intervention improved health and provided good value compared with the EUC intervention. The 6-month CHW-led DSME intervention without further postintervention CHW support was not cost-effective in Latino adults with T2D.**


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Approximately 30 million people in the U.S. have diabetes, and 1.5 million are diagnosed with diabetes each year (1). The total cost of diagnosed diabetes in the U.S. reached $327 billion in 2017, accounting for 24% of all health care expenditures (2). Evidence has demonstrated the short-term (e.g., 6 month) effectiveness of diabetes self-management education (DSME) in improving clinical outcomes and quality of life (3–6). DSME is associated with increased use of primary and preventive services and lower use of inpatient hospital services and is cost-effective (7). The American Diabetes Association recommends that all individuals with type 2 diabetes (T2D) receive DSME. However, given the number of people with diabetes, the limited number of diabetes educators, and inequities in access to high-quality care, the current health system cannot support long-term DSME (8).

Efforts have shifted to community resources to meet these challenges (9). Increasingly, community health workers (CHWs) have been used to provide structured DSME, especially in low-income and racial/ethnic minority communities and populations (10) where effective, culturally tailored approaches to diabetes self-management are needed (11,12). CHWs are trusted members of their communities and may relate to and empathize with their clients on a level that a credentialed health care professional may not (13,14).

Diabetes self-management support (DSMS) is defined as "activities that assist the individual with diabetes to implement and maintain the on-going behaviors needed to manage their illness." (5) The type of support provided can be behavioral, educational, psychosocial, and/or clinical in nature. Although CHWs have been shown to improve short-term self-monitoring, self-care, lifestyle change, and blood glucose control (5,6,13,15,16), it has been challenging to maintain the gains over the long term. Most patients require DSMS. One promising approach is to offer less intensive support services using peer leaders (PLs) after intensive CHW interventions (6,13,16–20). PLs share important characteristics with participants, including having diabetes. They are often volunteers or receive small stipends to reimburse any expenses (17,18,21). Some PL-led interventions have resulted in improvements in $HbA_{1c}$, self-empowerment scores, self-care indicators (16), patient activation (17), and diabetes-related distress (17). The most effective diabetes PL models offer support following structured DSME (6,10,18,20), are delivered through multiple modes of interaction (10), and are implemented in community settings.

The Racial and Ethnic Approaches to Community Health (REACH) Detroit Partnership, in collaboration with a federally qualified health center (Community Health and Social Services Center [CHASS]) adapted a DSME curriculum from the Diabetes Prevention Program using a community-based participatory approach (11,12), implemented it using trained CHWs, and tested it over several phases (5,6,22). Between October 2009 and February 2013, CHASS and the University of Michigan used this curriculum (Journey to Health/El Camino a la Salud) to conduct a cluster randomized clinical trial of a CHW-led DSME intervention to improve diabetes self-management, glycemic control, and other clinical and psychosocial outcomes among Latino adults with T2D receiving health care at CHASS (6). The trial enrolled 222 individuals with T2D who were first randomized to the CHW-led, 6-month DSME program ($n = 149$) or enhanced usual care (EUC) ($n = 73$). The CHW intervention included *1*) 11 Journey to Health/El Camino a la Salud DSME classes, *2*) a CHW-accompanied clinic visit to the participant and his or her primary care provider, *3*) support from the CHW for goal setting, and *4*) home visits and biweekly phone calls. The CHWs were Latinas from the southwest Detroit community who were fluent in Spanish and had received core competency CHW training, diabetes education training, and behavior modification strategies (6). The EUC group attended a 2-h class conducted by a research assistant that covered the interpretation of clinical and anthropometric information. Both groups received usual care at CHASS. At the end of the 6-month DSME program, the CHW-led group was further randomized to receive *1*) brief monthly check-in phone calls from the CHW between 7 and 12 months and no CHW contact from 13 to 18 months (CHW-only) ($n = 89$) or *2*) 12 months of weekly in-person group sessions of DSMS delivered by PLs (CHW + PL) ($n = 60$). All groups, including the EUC group, continued to receive usual care. The PLs were prior Journey to Health/El Camino a la Salud participants who completed PL training, received monthly booster sessions, and were supervised by the CHWs. This PL intervention component was added to the original design of the trial as a pilot study. The trial showed that participants in the CHW intervention at the 6-month follow-up had significant reductions in $HbA_{1c}$ and diabetes distress compared with EUC. CHW + PL participants maintained $HbA_{1c}$ improvements at 12 and 18 months, and CHW-only participants maintained improvements in diabetes distress at 12 and 18 months. Details of the study design, interventions, and results have been published elsewhere (6).

To date, for the management of T2D, there is no published research evaluating the cost-effectiveness of CHW + PL DSME/DSMS interventions, and there are limited studies that assessed the cost-effectiveness of CHW-only interventions (23). We sought to extend the trial results using a computer simulation model to estimate the longer term costs and health outcomes and to assess the long-term cost-effectiveness of the interventions, especially the cost-effectiveness of adding PL DSMS after a short-term intensive CHW-led DSME intervention.

## RESEARCH DESIGN AND METHODS

### Simulation Model

We used a validated microsimulation model for T2D, the Michigan Model for Diabetes (MMD) version 2.0 (24–27), to simulate the long-term cost-effectiveness of the CHW + PL intervention compared with EUC and the CHW-only intervention. Disease progression in the MMD is based on six discrete-time discrete-event submodels that simulate diabetes-related complications (retinopathy, nephropathy, neuropathy), major comorbidities (coronary heart disease, cerebrovascular disease), and death. Transition probabilities in these submodels are functions of individual characteristics, risk factor levels, and current disease and treatment states. The model also estimates the costs of diabetes and the health-related quality of life associated with the health states. Details

of the MMD have been published elsewhere (24–27).

### Simulation Population Characteristics and Modeled Health Outcomes

We incorporated information about the characteristics of the REACH Detroit trial participants and the effectiveness of the trial interventions into the MMD. The published analyses revealed that at 6 months after randomization, $HbA_{1c}$ decreased significantly more in participants who received the CHW intervention compared with those who received EUC (6). From 6 to 12 and 12 to 18 months, improvements in $HbA_{1c}$ were sustained for participants randomized to the CHW + PL group but not for those randomized to the EUC or the CHW-only groups (6). In addition, significant decreases in systolic blood pressure (SBP), diastolic blood pressure (DBP), and LDL cholesterol (LDLc) were observed in the CHW + PL group at 18 months compared with baseline. The time horizon for the simulation began at the end of the REACH Detroit trial (i.e., 18 months following randomization). For risk factors with significant within- or between-group differences (i.e., $HbA_{1c}$, SBP, DBP, and LDLc), group-specific summary statistics at 18 months were used as the initial simulation population characteristics. For all other variables (e.g., BMI, HDL cholesterol [HDLc], health utility scores), summary statistics that are based on the pooled population at 18 months were used for the simulation (Supplementary Table 1).

Continuous measures at 18 months following randomization were simulated using a Gaussian distribution with the given mean (median) and SD but truncated at ±3 SDs. Height and weight were simulated with a correlation of 0.51. SBP and DBP were simulated with a correlation of 0.82. Highly skewed distributions, such as $HbA_{1c}$ and triglyceride levels, were simulated using log-normal distributions.

To evaluate the long-term effectiveness and cost-effectiveness of the interventions, we estimated the incidence of clinical outcomes, life expectancy, and quality-adjusted life expectancy (QALE). The seven clinical outcomes included three-point major adverse cardiovascular events (MACE) (including nonfatal myocardial infarction [MI], nonfatal stroke, or cardiovascular death) and defined as the primary outcome, fatal or nonfatal MI, fatal or nonfatal stroke, coronary revascularization procedures, hospitalization for heart failure, death as a result of cardiovascular causes, and all-cause mortality.

### Intervention and Outcome Costs

We considered both the costs of implementing the interventions (intervention costs) and the medical costs of T2D and its complications (outcome costs) in the cost-effectiveness analyses. To estimate intervention costs, we included the costs of *1*) the 2-h class for the EUC group, *2*) identifying and training PLs, and *3*) implementing and maintaining CHW-only and CHW + PL interventions. These costs were summed to derive the total intervention costs. The per-participant intervention costs were $1,599, $820, and $234 for the CHW + PL, CHW-only, and EUC groups, respectively, over 18 months (Supplementary Table 2).

Outcome costs refer to the medical costs of T2D and its complications (Supplementary Table 3). We did not consider the medical costs of care incurred or averted by the interventions within the 18 months of the trial because the observed utilization of medical services (hospital, emergency department, and outpatient visits) and the use of prescription medications for hyperglycemia, hypertension, and dyslipidemia were not significantly different among the CHW + PL, CHW-only, and EUC groups. Outcome costs were estimated from the MMD on the basis of the published literature (28). Costs were assessed according to sex, BMI, antihyperglycemic therapy, and diabetes-related complications. The costs of complications were estimated as the cost incurred during the first year that a complication occurred (event cost) and the cost in each subsequent year after the complication occurred (ongoing cost). We also considered the costs of death.

Following the recommendations of the Second Panel on Cost-Effectiveness in Health and Medicine (29), we performed cost-effectiveness analyses from the health care sector perspective that considered medical costs (the intervention and outcome costs) borne by third-party payers. The impact inventory is provided in Supplementary Table 4. All costs were expressed in 2018 U.S. dollars.

### Health Utilities

Health utility scores are a measure of health-related quality of life in which perfect health is assigned a value of 1.0 and death a value of 0.0. In economic analyses, the health utility score for each health state is multiplied by the time a subject spends in that health state. These are then summed to calculate the QALE, which is expressed as quality-adjusted life-years (QALYs) accrued over a specified period of time. The MMD incorporates a health utility module to calculate yearly and cumulative QALYs on the basis of subjects' demographic, diabetes treatment, complication, and comorbidity status (27,30).

### Base-Case Analysis and Sensitivity Analyses

In the base-case analysis, we assumed that no additional interventions were implemented after 18 months and that the effects of the interventions observed at 18 months diminished over the simulation time horizon. Under this scenario, intervention costs only included the costs incurred over the 18-month trial period. We projected trajectories of $HbA_{1c}$, blood pressure, and lipid ratio (total cholesterol/HDLc) after 18 months according to the equations derived from the UK Prospective Diabetes Study Outcomes Model (UKPDS-OM) (31), which demonstrated gradual convergence of each risk factor as the treatment effect/benefit wore off.

In all analyses, we used a 20-year simulation time horizon. We also ran the MMD simulation for 10 years and 30 years to assess the shorter- and longer-term cost-effectiveness of the interventions, respectively. We minimized the first-order uncertainty (stochastic uncertainty) by performing Monte Carlo simulations with a large enough number of replications (3,000,000) for each of the three intervention groups so that the mean simulated event rates were stable (SEs ∼0.01–0.03). We assessed the cost-effectiveness of the CHW + PL intervention relative to the EUC and CHW-only interventions using incremental cost-effectiveness ratios (ICERs) calculated as incremental costs divided by

incremental QALYs. We also assessed the cost-effectiveness of the CHW-only intervention relative to EUC. We discounted both costs and QALYs at 3% per year.

Second-order uncertainty (parameter uncertainty) was assessed through sensitivity analyses. In the first two sensitivity analysis scenarios, we assumed that the intervention effects observed at 18 months persisted over the simulation time horizon and that the levels of risk factors (i.e., $HbA_{1c}$, blood pressure, lipids) did not change over time. In the first scenario, we assumed that no additional resources were needed to maintain the level of these risk factors and that the intervention costs included only the costs incurred over the 18-month trial period. This is an optimistic assumption. In the second scenario, we assumed that resources were needed to maintain the intervention benefit after 18 months. Therefore, we included ongoing intervention costs and assumed that 2 h per participant per year were required for the PL or CHW over the simulation time horizon. Under the assumption that effects of the interventions observed at 18 months diminished over the simulation time horizon (same as in the base-case analysis), we also performed one-way sensitivity analyses to assess the impact of cost and treatment effect parameters on the 20-year cost-effectiveness of the CHW + PL versus the EUC interventions (Supplementary Table 5). For the cost parameter, we assumed a 50% reduction or a 50% increase in intervention costs for the CHW + PL intervention. For the treatment effect parameters, the mean initial level of $HbA_{1c}$ in the CHW + PL group was increased or decreased by 1 SE of the estimated difference in change of $HbA_{1c}$ from randomization to 18 months postrandomization between the CHW + PL and EUC groups. The mean levels of SBP and LDLc were adjusted in the same manner.

All simulations were performed using Indirect Estimation and Simulation Tools software (32). Results from the simulation of the three intervention groups were evaluated using SAS statistical software (SAS Institute, Cary, NC).

There are no absolute criteria for cost-effectiveness in the U.S., and the long-cited benchmark of $50,000 per QALY gained for an intervention to be deemed cost-effective is largely unsupported (33). Nevertheless, in general, interventions costing <$20,000 per QALY gained may be considered as having strong evidence for adoption, interventions costing $20,000–$100,000 per QALY gained have moderate evidence for adoption, and those costing >$100,000 per QALY gained have weaker evidence for adoption (34). It has been suggested that a threshold of $100,000 or $150,000 per QALY gained may better reflect the U.S. health care environment (35) and represent good value for money.

## RESULTS

Supplementary Table 1 shows the characteristics of the three study groups at the end of the 18-month trial and the characteristics of the three simulated groups at the initiation of the model simulation. The simulated population of adults with T2D reflected the pooled sample means from the three study groups. The simulated Latino population had a mean age of 50.4 years, 39% were male, mean T2D duration was 7.6 years, and mean BMI was 32.4 kg/m$^2$. At the end of the trial, the CHW + PL group had the lowest $HbA_{1c}$, SBP, DBP, and LDLc; the CHW-only group had the highest SBP and DBP; and the EUC group had the highest $HbA_{1c}$ and LDLc. Figure 1 shows the gradual convergence of risk factors for diabetes progression over the simulation period in the base-case scenario. The magnitude of the difference in risk factors among the three groups become smaller over time.

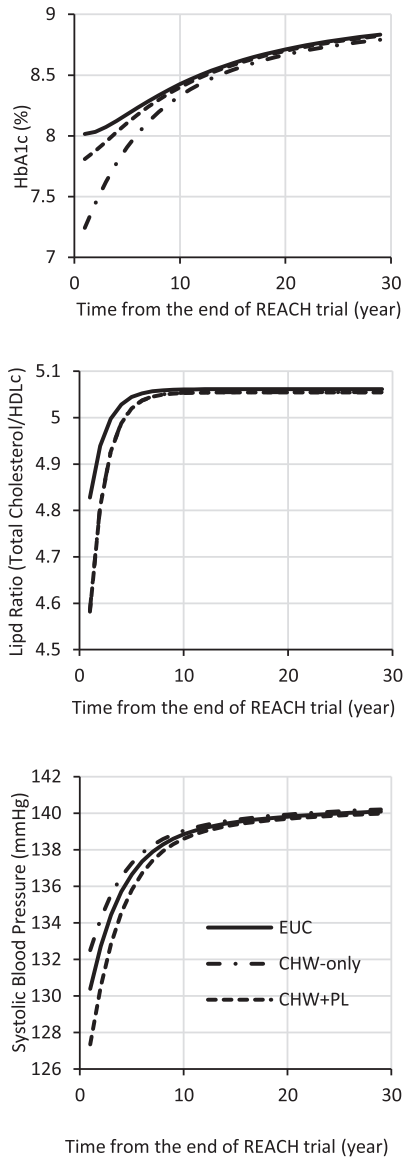


**Figure 1**—Simulated risk factor trajectories for the scenario assuming the diminishing intervention benefit after the end of the REACH Detroit trial and over the simulation period.

### Health Outcomes

Table 1 summarizes the simulated 20-year cumulative incidence of diabetes complications by intervention group. In the base-case scenario with diminishing intervention benefit overtime, clinical outcomes were generally best for the CHW + PL intervention group and worse for the CHW-only and EUC intervention groups. For example, the cumulative incidence of three-point MACE was lowest in the CHW + PL group (30.1%) and higher in the CHW-only (30.5%) and EUC groups (30.6%). In the scenario in which we assumed persistent intervention benefits, clinical outcomes were best for the CHW + PL intervention group and worse for the CHW-only or EUC intervention groups. For example, the cumulative incidence of three-point MACE was lowest in the CHW + PL group (23.6%) followed by the CHW (26.1%) and EUC groups (26.9%). The cumulative incidence of stroke was lowest in the CHW + PL group (5.1%) followed by the EUC (6.0%) and CHW-only groups (6.1%).

### Cost-Effectiveness

Table 2 summarizes the simulated outcomes for the base-case analysis. Over a 20-year period, the CHW + PL

**Table 1—Cumulative incidence of complications when intervention effects diminish or persist over 20 years by intervention group**

| | Scenario with diminishing intervention effects[1], % | | | Scenario with persistent intervention effects[2], % | | |
|---|---|---|---|---|---|---|
| Complication | EUC | CHW only | CHW + PL | EUC | CHW only | CHW + PL |
| MI | 14.5 | 14.4 | 14.1 | 12.6 | 12.0 | 10.7 |
| Stroke | 7.3 | 7.3 | 7.1 | 6.0 | 6.1 | 5.1 |
| Cardiovascular death | 21.0 | 20.9 | 20.6 | 18.6 | 18.0 | 16.1 |
| Three-point MACE | 30.6 | 30.5 | 30.1 | 26.9 | 26.1 | 23.6 |
| Revascularization procedure | 24.9 | 24.7 | 24.3 | 22.0 | 21.1 | 19.3 |
| Congestive heart failure | 18.1 | 18.2 | 18.1 | 17.3 | 17.2 | 16.3 |
| All-cause death | 34.3 | 34.3 | 34.0 | 32.2 | 31.6 | 30.0 |

[1]We used the UKPDS-OM risk equations to project gradual convergence trajectories of the postintervention levels of all risk factors for diabetes complications (i.e., $HbA_{1c}$, SBP, and lipid ratio [total cholesterol divided by HDLc]) as the treatment effect wears off over a period of several years. [2]We assumed that the postintervention levels of all risk factors for diabetes complications (i.e., $HbA_{1c}$, SBP, and lipid ratio [total cholesterol divided by HDLc]) did not change over the simulation time horizon.

intervention was associated with the longest life expectancy (17.06 years) and QALE (7.07 QALYs). The EUC intervention resulted in the lowest total costs over 20 years ($127,639). Compared with the EUC group, the CHW + PL group cost $796 more and gained 0.028 more QALYs, leading to an ICER of ∼$28,800 per QALY gained. Compared with the CHW-only group, the CHW + PL group cost ∼$5,900 per QALY gained. Compared with the EUC group, the CHW-only group cost $641 more and gained 0.002 QALYs, resulting in an ICER of ∼$430,600 per QALY gained. Over the 10-year and 30-year time horizons, compared with the EUC invention, the CHW + PL group cost ∼$44,200 and $28,200 per QALY gained, respectively, and the CHW-only group cost ∼$4,443,300 and $402,600 per QALY gained, respectively.

Table 3 summarizes the results of the two sensitivity analyses. When we assumed that the intervention benefit observed at 18 months persisted over 20 years without further intervention, the CHW + PL group dominated both the EUC and the CHW-only groups. That is, the CHW + PL group cost $1,933 less and gained 0.092 more QALYs than the EUC group and cost $1,798 less and gained 0.071 more QALYs than the CHW-only group. Compared with the EUC group, the CHW-only group was also cost saving over 20 years. Compared with the EUC group, the CHW-only group produced an ICER of ∼$5,100 per QALY gained over 10 years

**Table 2—Base-case analysis modeling cost-effectiveness of interventions for 18 months with diminishing intervention benefits after 18 months**

| | EUC | CHW only | CHW + PL | CHW + PL vs. CHW only | CHW only vs. EUC | CHW + PL vs. EUC |
|---|---|---|---|---|---|---|
| Intervention cost[1] ($) | 234 | 820 | 1,599 | 779 | 586 | 1,365 |
| Outcome cost ($) | | | | | | |
| 10 years | 71,934 | 71,899 | 71,226 | –674 | –35 | –708 |
| 20 years | 127,405 | 127,460 | 126,836 | –624 | 55 | –569 |
| 30 years | 163,073 | 163,164 | 162,644 | –520 | 92 | –428 |
| Total cost ($) | | | | | | |
| 10 years | 72,168 | 72,719 | 72,825 | 105 | 551 | 657 |
| 20 years | 127,639 | 128,280 | 128,435 | 155 | 641 | 796 |
| 30 years | 163,307 | 163,984 | 164,243 | 259 | 678 | 937 |
| Life expectancy (years) | | | | | | |
| 10 years | 9.35 | 9.36 | 9.38 | 0.019 | 0.0040 | 0.0236 |
| 20 years | 17.01 | 17.02 | 17.06 | 0.0478 | 0.0091 | 0.0569 |
| 30 years | 22.65 | 22.66 | 22.72 | 0.0692 | 0.0096 | 0.0788 |
| QALE (QALYs) | | | | | | |
| 10 years | 4.46 | 4.46 | 4.48 | 0.0147 | 0.0001 | 0.0149 |
| 20 years | 7.05 | 7.05 | 7.07 | 0.0262 | 0.0015 | 0.0276 |
| 30 years | 8.40 | 8.41 | 8.44 | 0.0316 | 0.0017 | 0.0333 |
| Cost per QALY gained ($) | | | | | | |
| 10 years | | | | 7,168 | 4,443,300 | 44,172 |
| 20 years | | | | 5,918 | 430,600 | 28,796 |
| 30 years | | | | 8,202 | 402,594 | 28,164 |

[1]Intervention cost was the per-participant cost over the 18-month intervention period of the REACH Detroit trial.

**Table 3—Sensitivity analyses modeling cost-effectiveness of interventions**

| Sensitivity analysis scenario | EUC | CHW only | CHW + PL | CHW + PL vs. CHW only | CHW only vs. EUC | CHW + PL vs. EUC |
|---|---|---|---|---|---|---|
| 18-month intervention with persistent intervention benefits | | | | | | |
| Total cost[1] ($) | | | | | | |
| 10 years | 70,851 | 70,878 | 69,985 | –893 | 27 | –866 |
| 20 years | 124,401 | 124,265 | 122,467 | –1,798 | –135 | –1,933 |
| 30 years | 159,312 | 159,367 | 157,491 | –1,876 | 54 | –1,822 |
| QALE (QALYs) | | | | | | |
| 10 years | 4.48 | 4.49 | 4.51 | 0.0234 | 0.0051 | 0.0286 |
| 20 years | 7.14 | 7.16 | 7.23 | 0.0714 | 0.0206 | 0.0919 |
| 30 years | 8.58 | 8.61 | 8.73 | 0.1183 | 0.0348 | 0.1532 |
| Cost per QALY gained ($) | | | | | | |
| 10 years | | | | Cost saving | 5,148 | Cost saving |
| 20 years | | | | Cost saving | Cost saving | Cost saving |
| 30 years | | | | Cost saving | 1,570 | Cost saving |
| Ongoing intervention with persistent intervention benefits | | | | | | |
| Total cost[2] ($) | | | | | | |
| 10 years | 70,851 | 71,252 | 70,545 | –706 | 400 | –306 |
| 20 years | 124,401 | 124,867 | 123,371 | –1,497 | 467 | –1,029 |
| 30 years | 159,312 | 160,109 | 158,604 | –1,505 | 796 | –709 |
| QALE (QALYs) | | | | | | |
| 10 years | 4.48 | 4.49 | 4.51 | 0.0234 | 0.0051 | 0.0286 |
| 20 years | 7.14 | 7.16 | 7.23 | 0.0714 | 0.0206 | 0.0919 |
| 30 years | 8.58 | 8.61 | 8.73 | 0.1183 | 0.0348 | 0.1532 |
| Cost per QALY gained ($) | | | | | | |
| 10 years | | | | Cost saving | 78,148 | Cost saving |
| 20 years | | | | Cost saving | 22,719 | Cost saving |
| 30 years | | | | Cost saving | 22,862 | Cost saving |

[1]Total cost was a combination of the intervention cost and outcome cost. The intervention cost was $234, $820, and $1,599 per participant for the EUC, CHW-only, and CHW + PL interventions, respectively, over the 18-month intervention period of the REACH Detroit trial. The outcome cost derived from the direct medical costs of diabetes and its complications was estimated by the MMD. [2]Total cost was a combination of the intervention cost and outcome cost. The intervention cost was $234, $820, and $1,599 per participant for the EUC, CHW-only, and CHW + PL interventions, respectively, over the 18-month intervention period of the REACH Detroit trial. The ongoing intervention cost per participant per year was $43.80 and $65.70 for the CHW-only and CHW + PL interventions over the simulation period, respectively, assuming that a total of 2 h per participant per year was required by the CHW or PL to make contact with the participants. The ongoing cost would support the ongoing CHW-only and CHW + PL interventions to maintain the trial-observed intervention effects over the simulation time horizon. The outcome cost derived from the direct medical costs of diabetes and its complications was estimated by the MMD.

and $1,600 per QALY gained over 30 years. Over the 10-year and 30-year time horizons, the CHW + PL group still dominated the other two groups.

In the second sensitivity analysis, we assumed that limited ongoing interventions were needed after 18 months to maintain the benefits observed at 18 months (Table 3). Under this assumption, over 20 years, the CHW + PL dominated both the EUC and the CHW-only groups. The CHW-only group compared with the EUC group yielded an ICER of ~$22,700 per QALY gained. Over the 10-year and 30-year time horizons, the CHW + PL group still dominated the EUC and CHW-only groups. The CHW-only group cost ~$78,100 and ~$22,900 per QALY gained, respectively, compared with the EUC group.

Supplementary Table 5 shows the effects of plausible changes in the intervention costs and treatment effects of the CHW + PL intervention on cost-effectiveness under the assumption that effects of the interventions observed at 18 months diminished over the simulation time horizon. Compared with the EUC intervention, a 50% reduction in the intervention costs would make the CHW + PL intervention cost saving. A 50% increase in the intervention costs would increase the ICER of the CHW + PL intervention to ~$57,700 per QALY gained. When we assumed a smaller treatment effect on one of the three key risk factors, the ICER of CHW + PL versus EUC increased, ranging from $37,600 to $46,092 per QALY gained. When assuming a larger treatment effect on one of the three key risk factors, the ICER decreased, ranging from $15,000 to $18,400 per QALY gained.

## CONCLUSIONS

In this study, we showed that a CHW + PL–led DSME/DSMS intervention in Latino adults with T2D and poor glycemic control in a low-income urban setting was cost-effective compared with EUC. In the base-case scenario, compared with the EUC strategy, the CHW + PL strategy cost ~$28,800 per QALY gained over 20 years by preventing diabetes-related complications and death. Compared with the EUC strategy, the CHW-only strategy was not cost-effective ($430,600 per QALY gained) because of the dissipation of the intervention effects between 6 and 18 months. The

effectiveness of the PLs in maintaining the benefits of the intensive CHW-led DSME program, and its relatively low cost, accounted for it being cost-effective. When compared with the CHW-only strategy, the CHW + PL strategy is highly cost-effective ($5,900 per QALY gained).

Our study is among the first to use a validated computer simulation model that is based on information from a short-term randomized controlled trial to evaluate the long-term cost-effectiveness of a CHW intervention. A systematic review (23) identified three published cost-effectiveness analyses of CHW interventions for T2D management using computer simulation modeling. They showed that a CHW intervention compared with usual care costs from $371 to $127,000 per QALY gained over a 20-year simulation time horizon from health system or societal perspectives. In contrast, the CHW-only intervention was not cost-effective in our base-case analysis. Given that two of the previously published studies mentioned above used very different designs, we only consider the third Community Diabetes Education (CoDE) (36) study for comparison. First, the CHW-led DSME intervention in the REACH Detroit trial was only 6 months, shorter than the 12-month intervention period in the CoDE trial. In the REACH Detroit trial, only brief CHW telephone contacts were made between 7 and 12 months followed by no further CHW contact between 13 and 18 months, which likely contributed to the waning effects in this group. Compared with the EUC intervention at 18 months, the CHW-only intervention was associated with lower $HbA_{1c}$ and lipid levels but higher blood pressure levels, leading to a mixed and smaller impact on the incidence of some diabetes complications (e.g., stroke, congestive heart failure). This translated into a tiny improvement in QALYs, resulting in a large ICER for the CHW intervention compared with the EUC intervention in our base-case analysis.

In the base-case analyses, we found that relative to the EUC intervention, the CHW + PL intervention was cost-effective, but the CHW-only intervention was not. The improvements attributable to the 6-month CHW-led DSME intervention in risk factors, including $HbA_{1c}$ and SBP, were maintained or even greater in the CHW + PL group but not maintained at 18 months in the CHW-only group. This led to a lower incidence of diabetes-related complications in the CHW + PL group compared with the CHW-only group (Table 1), which averted downstream outcome costs and produced greater QALYs (Table 2). The additional support provided by PLs to the CHW + PL intervention group came at a relatively low cost. It follows that compared with the EUC intervention, the CHW + PL intervention was more economically attractive than the CHW-only intervention.

When we assumed that the benefits observed at 18 months after randomization persisted over 20 years, the CHW-only intervention was cost saving compared with the EUC intervention if no additional interventions were needed and cost-effective ($22,700 per QALY gained) if limited additional interventions were needed. The assumption that the benefits observed at 18 months after randomization persisted over the 20-year simulation period is likely to be overly optimistic. The estimated cost-effectiveness of the CHW-only intervention relative to the EUC intervention was sensitive to assumptions regarding the persistence of the intervention benefits.

Some limitations to our study should be acknowledged. First, no simulation model can perfectly represent reality, and all models have inherent limitations (37). The validity of our modeling results are contingent on data quality and model assumptions. Misspecification of model parameters and structure are generally the most important sources of uncertainty. We have minimized first-order (stochastic) uncertainty and population uncertainty. To evaluate second-order (parameter) uncertainty, we also conducted sensitivity analyses to vary the costs and the treatment effects of the CHW + PL intervention. Our previous studies have demonstrated very good performance of the MMD (25). For this study, we used version 2 of the MMD, recalibrated the model parameters, and performed both internal and external validation studies to verify the model's performance. Second, the results that we simulated were based on a clinical trial and may not represent diabetes management in real-world practice. Our study participants were Latino adults with T2D from a low-income urban setting. This may limit the generalizability of our findings. However, because Latino Americans experience a greater burden of diabetes complications than other racial/ethnic groups, the results obtained through this simulation study may have underestimated the long-term health and economic benefits (36). Finally, the cost-effectiveness analyses from the societal perspective were not performed because the cost data were unavailable from the informal health care and non–health care sectors, as shown in the impact inventory (Supplementary Table 4).

In summary, for Latino adults with T2D and poor glycemic control in a low-income urban setting, we found that adding a 12-month, less intensive PL-led DSMS intervention after a 6-month CHW-led DSME intervention was cost-effective relative to both EUC and a CHW-only intervention. In some sensitivity analyses, this hybrid CHW + PL–led DSME/DSMS intervention could be cost saving. A 6-month intensive CHW-led DSME intervention with only limited follow-up was not cost-effective compared with EUC. Our pilot study of PL-led DSMS contributes to the literature supporting the use of such hybrid interventions. Larger clinical trials with longer follow-up are warranted to confirm and generalize these findings. From the perspective of a financially prudent policymaker, the CHW + PL intervention represents a good value for money. Health policy should support funding and reimbursement models for CHW + PL–led intervention programs.

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